UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

GLENDA JIMMO, KR by her guardian KENNETH ROBERTS, MIRIAM KATZ, EDITH MASTERMAN, MARY PATRICIA BOITANO, NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE, NATIONAL MULTIPLE SCLEROSIS SOCIETY, PARKINSON'S ACTION NETWORK, PARALYZED VETERANS OF AMERICA, and AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION, on behalf of themselves and all others similarly situated, Plaintiffs, vs. KATHLEEN SEBELIUS, Secretary of Health and Human Services, Defendant.	Civil Action No. 5:11-cv-17 COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND MANDAMUS RELIEF CLASS ACTION

I. PRELIMINARY STATEMENT

1. This is an action for declaratory, injunctive, and mandamus relief against the Secretary of Health and Human Services (the Secretary) as the official responsible for implementing and enforcing the Medicare program. Under the Medicare statute and regulations, coverage is available for health care and therapy services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." This standard requires the evaluation for coverage on the basis of a beneficiary's unique condition and

individual needs. The Secretary, however, imposes a covert rule of thumb that operates as an additional and illegal condition of coverage and results in the termination, reduction, or denial of coverage for thousands of Medicare beneficiaries annually.

2. This additional condition of eligibility, which is usually implemented at the lower levels of Medicare's administrative review process where the overwhelming majority of decisions are made, is referred to and implemented by one or more of several phrases, including that the beneficiary needs "maintenance services only," has "plateaued," or is "chronic," "medically stable," or not improving. The shorthand term for this rule of thumb masquerading as a condition of coverage is the Improvement Standard.

3. The Improvement Standard is not supported by the Medicare statute or regulations. Because it has been implemented without notice-and-comment rulemaking and without publication in the Federal Register, beneficiaries have little or no understanding of its application and cannot know, and/or do not have the resources, to seek further review. Despite numerous court decisions repudiating the Improvement Standard and dictating that each beneficiary's situation should be evaluated on an individualized basis, the Improvement Standard continues to be applied, especially by employees of Medicare contractors and intermediaries who ignore the correct coverage standards. The regular, on-going application of the Improvement Standard in this context amounts to a clandestine policy that is condoned and implemented by the Secretary.

4. The impact of the Improvement Standard falls primarily on patients with chronic conditions. As their health deteriorates their need for nursing services and physical, occupational, and speech therapies increases. The skilled care denied them

under the Improvement Standard is critical to slow their disease process and to maintain their functional ability, yet these are precisely the patients who are most likely to have their coverage denied, terminated, or reduced.

5. The Improvement Standard operates as a covert condition of coverage that simultaneously deprives beneficiaries of coverage to which they are entitled while effectively denying them the ability to correct its application. It violates the Medicare statute and regulations, the Administrative Procedure Act's and the Medicare statute's requirements for notice-and-comment rulemaking, the Freedom of Information Act's requirement of publication, and the Due Process Clause of the Fifth Amendment.

6. On behalf of themselves, their members and constituents, and the nationwide class of Medicare beneficiaries whom they represent and who are harmed by the Improvement Standard, the plaintiffs -- national organizations and individual beneficiaries -- seek declaratory, injunctive, and mandamus relief to terminate application of the Improvement Standard and to provide remedies to those illegally denied coverage as a result of its application.

II. JURISDICTION AND VENUE

7. Jurisdiction is conferred on this court by 28 U.S.C. §§ 1331 and 1361 and by 42 U.S.C. § 405(g), as incorporated by 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395w-22(g)(5). Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) and 42 U.S.C. § 405(g).

III. PARTIES

8. Plaintiff GLENDA JIMMO was born in 1936 and is a resident of Bristol, Vermont. At all relevant times she has been eligible for Medicare Parts A and B. A

decision by an administrative law judge, dated June 16, 2010, denied her coverage for home health services furnished to her between January 14, 2007 and January 8, 2008. That decision was affirmed by the Medicare Appeals Council in a decision dated December 28, 2010.

9. Plaintiff KR was born in 1960 and is a resident of Bennington, Vermont. She is represented in this action by her guardian. At all relevant times she has been eligible for Medicare Parts A and B. A decision by an administrative law judge, dated November 16, 2010, denied her coverage for home health skilled therapy services provided from September 26, 2008 to December 18, 2008. That decision was appealed to the Medicare Appeals Council on December 22, 2010.

10. Plaintiff MIRIAM KATZ, the widow of David Katz, is named as the executor in his will. David Katz was born in 1920 and was a resident of Bloomfield, Connecticut before he died on December 25, 2010. At all relevant times he was eligible for Medicare Parts A and B. In a reconsideration decision on expedited review by a Qualified Independent Contractor on December 3, 2010, coverage for his skilled nursing facility care was denied beginning December 1, 2010.

11. Plaintiff EDITH MASTERMAN was born in 1931 and lives in Wilton, Maine. At all relevant times she was eligible for Medicare Parts A and B. Because the only Medicare certified home health agency in her area has determined, pursuant to the Improvement Standard, that she would not be covered under Medicare for its services, she cannot receive care from that agency, obtain an initial Medicare determination that those services are not covered, or appeal the denial of Medicare coverage.

12. Plaintiff MARY PATRICIA BOITANO was born in 1927 and is a

resident of Narragansett, Rhode Island. Ms. Boitano is eligible for Medicare Parts A and B, and was at all relevant times enrolled in a Part C Medicare Advantage program, Secured Horizons (also known as "United HealthCare"). In a decision on a "fast-track" appeal on November 22, 2010, Medicare coverage for her skilled nursing facility care was denied beginning November 23, 2010.

13. Plaintiff NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE is a nationwide membership organization, headquartered in Washington, D.C., that seeks to protect and preserve the financial security, health, and well being of current and future generations of maturing Americans.

14. Plaintiff NATIONAL MULTIPLE SCLEROSIS SOCIETY is a nationwide organization, headquartered in New York, N.Y., that seeks to eradicate multiple sclerosis by stopping disease progression and preventing the disease in future generations, while restoring function and providing and advocating for enhanced care and support for those already affected by or living with this chronic disease.

15. Plaintiff PARKINSON'S ACTION NETWORK is a nationwide organization, headquartered in Washington, D.C., that seeks to eliminate Parkinson's disease and to improve the quality of life for people living with it.

16. Plaintiff PARALYZED VETERANS OF AMERICA is a nationwide membership organization, headquartered in Washington, D.C., that seeks to find cures for spinal cord injury and spinal disease and to improve the quality of life for its members and for all people with spinal cord injury or disease.

17. Plaintiff AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION is a nationwide physician membership organization, headquartered

in Rosemont, Ill., that advocates on behalf of its members, whose specialty is physical medicine and rehabilitation, and on behalf of those with injuries, pain, and disabling conditions whom its members serve.

18. Defendant KATHLEEN SEBELIUS is the Secretary of Health and Human Services (HHS) and is responsible for the overall operation of the Medicare program through the HHS division known as the Centers for Medicare & Medicaid Services (CMS). She is sued in her official capacity.

IV. CLASS ACTION ALLEGATIONS

19. Plaintiffs bring this action on behalf of themselves and all others similarly situated, pursuant to Rules 23(a) and (b)(2) of the Federal Rules of Civil Procedure. The class is defined as:

> All beneficiaries of Medicare Parts A, B, or C who have had or will have coverage for health care or therapy services, as an outpatient, in a hospital, in a skilled nursing facility, or in a home health care setting, denied, terminated, or reduced due to the application of the Improvement Standard, on or after January 1, 2006.

20. Joinder is impracticable due to the large number of class members and for other reasons, including, but not limited to, their geographic diversity, their ages and/or disabilities, and their relatively low incomes. On information and belief, plaintiffs estimate the class to include at least tens of thousands of members.

21. There are questions of fact and law common to the class members. Common facts include, *inter alia*, that all class members have had their Medicare

coverage reduced, denied, or terminated on the ground that their conditions were not improving. The common questions of law include, *inter alia*, whether the Secretary violates the Medicare statute in imposing this covert condition of eligibility and whether that policy has been implemented in violation of procedural rules such as the notice-and-comment requirements of the Administrative Procedure Act and the Medicare statute.

22. The claims of the named plaintiffs are typical of those of the class members in that they have been denied Medicare coverage, despite satisfying the statute's reasonable and necessary requirement, because of the application of the Improvement Standard.

23. The named plaintiffs will fairly and adequately protect the interests of the class. They have no interest that is or may be potentially antagonistic to the interests of the class and seek the same relief as the class members, that is, a prohibition against the continued use of the Improvement Standard. Moreover, plaintiffs are represented by competent counsel from established public interest law firms, the Center for Medicare Advocacy, Inc. and the Medicare Advocacy Project of Vermont Legal Aid. The attorneys are experienced in federal litigation involving public benefit programs in general and Medicare in particular, have litigated other cases involving the Improvement Standard, and have represented classes in numerous other cases involving Medicare and other public benefit programs.

24. The Secretary has acted and continues to act on grounds generally applicable to the class as a whole, thereby making appropriate final injunctive and declaratory relief with respect to the class as a whole, pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure.

V. LEGAL FRAMEWORK

A. Overview

25. Medicare, which is codified as Title XVIII of the Social Security Act, is the federally funded and administered program of health insurance for those who are 65 and over or are disabled. Under Part A of Medicare, for which eligibility is automatic for recipients of Social Security old age and disability benefits (Title II of the Social Security Act), beneficiaries are entitled to coverage for hospital, skilled nursing facility care, home health care, and hospice services. Part B of Medicare establishes a voluntary program of supplemental medical insurance providing coverage for physicians, nurse practitioners, home health, physical, speech and occupational therapy, diagnostic services, and durable medical equipment. Under Part C (the Medicare Advantage program), beneficiaries may opt to enroll in a managed care plan in lieu of the traditional approach in "original Medicare" as provided in Parts A and B.

26. The threshold for Medicare coverage is its medical necessity requirement, which states in applicable part that "no payment may be made … for any expenses incurred for items or services which … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

27. Other than the reference in the last clause of subsection 1395y(a)(1)(A) to coverage for "improv[ing] the functioning of a malformed body member," the Medicare statute does not state or imply at any point that improvement, or any comparable phraseology, is a condition of coverage.

B. The Regulatory Requirements

28. The relevant regulation for coverage in the skilled nursing facility (SNF) context makes it clear that the Improvement Standard does not determine coverage: "The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities." 42 C.F.R. § 409.32(c). The regulations applicable to coverage of home health care incorporate by reference the definition of skilled nursing care and thus the above standard. 42 C.F.R. § 409.44(b)(1).

29. The regulations further dictate, in defining the "reasonable and necessary" standard, that the individual's "unique" situation is the cornerstone for coverage. The home health regulation states in part: "The intermediary's decision on whether care is reasonable and necessary is based on information … concerning the unique medical condition of the individual beneficiary." 42 C.F.R. § 409.44(a). It further dictates that "[t]he determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time." 42 C.F.R. § 409.44(b)(3)(iii).

30. The home health regulations related to physical, speech, and occupational therapy provide for Medicare coverage for services to restore or to maintain function. 42 C.F.R. § 409.44(c)(2).

31. Many of CMS' manual provisions support and reinforce the regulatory

prohibition against an Improvement Standard as a condition of coverage. The Medicare Benefit Policy Manual (MBPM) states that the determination of whether a skilled service is reasonable and necessary cannot be based on "rules of thumb," but instead requires assessment of the particular individual's need for care. Internet Only Manual (IOM) 100-02, MBPM, ch. 7, §§ 20.3, 40.2. The Manual reiterates the regulatory language requiring assessment "of the beneficiary's unique condition and individual needs" and adds that "skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable." *Id.*, § 40.1.1.

32. Lower level decision-makers, however, rarely follow these regulatory and Manual prohibitions against the Improvement Standard. Instead, they rely on other policy provisions, Medicare contractor instructions, and Local Coverage Determinations (LCDs). LCDs are created by individual contractors to provide guidance in those jurisdictions in which they operate. LCDs often employ language that enforces an Improvement Standard. *See, e.g.,* LCD ID # L23604 ("There must be an expectation that the condition will improve significantly in a reasonable and generally predictable period of time …."); LCD ID # L340 ("The documentation supports the expectation that the beneficiary's condition will improve significantly in a reasonable and generally predictable period of time."). As a rule, lower level decision-makers will rely on more restrictive internal guidelines, policies, and LCDs rather than on contrary regulations or Manual provisions. LCDs are not binding on administrative law judges.

C. The Administrative Review Process

33. Under original Medicare (Parts A and B), a beneficiary who has been informed by the provider that the services at issue are not expected to be covered must obtain an "initial determination" from the Medicare contractor. This formal statement of non-coverage is provided as part of the Medicare Summary Notice (MSN), which the contractors issue on a quarterly basis.

34. Under the standard review process, the beneficiary requests review of the MSN "initial determination" by filing for a redetermination by the Medicare contractor. If the decision remains adverse, the beneficiary may seek reconsideration from the Qualified Independent Contractor (QIC).

35. Under the expedited review process that is available for discharge from a SNF, home health care, or a hospice, the provider must generally give notice two days before the discharge or termination occurs. The beneficiary has until noon of the next calendar day to request an expedited determination by the Quality Improvement Organization (QIO). If the QIO upholds the provider's decision, the beneficiary has until noon of the next calendar day to seek reconsideration from the QIC.

36. The remaining steps are the same for both standard and expedited review. These include a de novo review by an administrative law judge (ALJ) if the amount in controversy is at least $130 in 2010 and 2011 and an on-the-record review of the ALJ's decision by the Medicare Appeals Council (MAC), with the same amounts in controversy. Review in federal district court is then available for cases in which the

amount in controversy is at least $1,300 in 2011.

37. For claims under Part C (the Medicare Advantage or MA program), the initial determination, which is known as an "organization determination," and the reconsideration determination, if fully favorable, are both made by the Medicare Advantage plan, in both the standard and expedited processes. When a reconsideration determination will be adverse to the beneficiary, the case is automatically sent to the Independent Review Entity (IRE), which is an external review organization hired by CMS for the purpose of reviewing decisions by MA plans and which will issue the reconsideration decision.

38. The remaining available steps after IRE review are the same as for Parts A and B: ALJ, MAC, and federal district court.

39. If the MAC fails to issue its decision within the appropriate time frames (which is usually 90 days from receipt of the request for review), the appellant may request escalation of the case to federal district court.

40. Under Parts A and B, a beneficiary cannot obtain a coverage decision prior to receiving the care. Consequently, access to and proceeding through the system of administrative review requires the beneficiary's obligation to pay for the care or services. Beneficiaries confronted with having to pay for care for which coverage may be denied often decline the needed care because their financial situation makes it difficult or impossible to pay. As a consequence, they are unable to obtain administrative review of their right to Medicare coverage. Under Part C, a beneficiary can receive a coverage

decision prior to receiving the care or services at issue.

D. Application of the Improvement Standard Below the ALJ Level

41. Upon information and belief, it is the standard practice of providers, contractors, QIOs, QICs, and IREs to apply LCDs and internal guidelines and policies that establish the Improvement Standard as a rule of thumb on which Medicare coverage is conditioned, in disregard of the regulatory and manual provisions that require a coverage determination to be based on the beneficiary's individual condition and needs. This approach holds true for decisions made under each of Parts A, B, and C.

42. The application of the Improvement Standard at the lower levels of review imposes an additional condition of eligibility. It has the twofold effect of denying coverage to beneficiaries who are entitled to it and discouraging them from seeking review because the Improvement Standard, as stated, appears to be impossible to overcome.

43. In 2008, only about 1.7% of all Part A denied claims and 1.8% of all Part B denied claims were appealed to the next level, the redetermination level. CMS, "Fact Sheet: Original Medicare (Fee-For-Service) Appeals Data – 2008," at 2, available at cms.gov/OrgMedFFSAppeals/Downloads/Feeshet2008.pdf. Only about 0.5% of Part A denied claims and 0.22% of Part B denied claims were appealed to the reconsideration level. *Id.* at 6. In FY 2008, the number of all Medicare appeals taken to ALJs was 32,960, which included 185,665 claims. Office of Medicare Hearings and Appeals website, at http://www.hhs.gov/omha/resources/index.html. Estimating and extrapolating

from these figures suggest that the percentage of adverse initial denials that reach the ALJ level is extremely small, probably in the range of 0.02% to 0.05%. Furthermore, the percentage of adverse initial determinations based on the Improvement Standard is probably lower still than the overall percentage because beneficiaries are less likely to appeal when the Improvement Standard is applied to them. They generally do not appeal because the Improvement Standard, as it is presented to them, suggests that they cannot succeed on appeal. Accordingly, on information and belief, only a minuscule percentage of beneficiaries who are denied based on the Improvement Standard appeal the denial to the ALJ level.

44. Upon information and belief, the Secretary is aware that the Improvement Standard is consistently imposed by her Medicare contractors but has not taken action to require that the proper policies be carried out. This refusal to correct the situation has occurred despite numerous federal court decisions repudiating the Improvement Standard as a condition of coverage.

VI. FACTUAL STATEMENT

Plaintiff Glenda Jimmo

45. During the periods at issue, plaintiff Glenda Jimmo was a 71-year-old resident of Vermont who was legally blind and had a below-the-knee amputation. She suffered from diabetes mellitus with circulatory disorder, transient cerebral ischemia, peripheral vascular disease, angina, and, later, diverticulitis. Transient cerebral ischemia is a serious disorder that could lead to a stroke or death of brain cells and may be caused

by uncontrolled diabetes. Peripheral vascular disease is also a serious disorder with the possibility of blood clots, open sores, and tissue death. Possible complications of angina include heart attack or death. During the time periods in question, Ms. Jimmo suffered chest pains. Her physician prescribed over twenty medications to address these disorders. These medications included nitroglycerine, an overdose of which can cause seizures or a coma.

46. As a result of her substantial, disabling medical conditions, her physician ordered intermittent skilled nursing and home health aide nursing services to be provided in her home. Her physician certified her need for these services on the plan of care and also certified that she was homebound.

47. Her claims for Medicare coverage for the home health services received from January 14, 2007 to January 8, 2008 were denied initially and at the redetermination level. In denying her coverage at redetermination, the Medicare contractor stated that "[h]er condition was stable with no acute changes."

48. At the reconsideration level of review, the QIC affirmed the denial of coverage, stating, *inter alia*, that "[t]he likelihood of a change in the patient's condition requiring skilled nursing services was not supported in the documentation."

49. A timely filed request for review by an ALJ resulted in a decision dated June 16, 2010 that she was not entitled to coverage under Part A for those services. In making that determination, the ALJ, like the lower level contractors before him, applied the Improvement Standard. He stated, *inter alia*, that "[o]bservation and assessment of

the Beneficiary was not necessary as the Beneficiary was stable .... The Beneficiary's condition did not significantly changes [*sic*] during the period at issue and the plan of care did not undergo changes."

50. Plaintiff Jimmo timely appealed the ALJ decision in a request to the MAC dated August 8, 2010. The decision of the MAC was due within 90 days of the MAC's receipt of the request for review. As of December 22, 2010, the decision had not been received. Accordingly, on that date plaintiff Jimmo sent a request by Federal Express overnight mail to the MAC that the case be escalated to district court.

51. By decision dated December 28, 2010 and received by plaintiff Jimmo on December 30, 2010, the MAC affirmed the decision of the ALJ. It agreed with the ALJ "that the wound care was not complex, the beneficiary was stable and seen frequently in her physician's office for lesions and debridement, and neither her condition nor the plan of care changed significantly during the period at issue." Accordingly, "[t]he Council sees no basis for changing the ALJ's decision. The Council therefore adopts the ALJ's decision."

Plaintiff KR

52. During the periods at issue, plaintiff KR, a resident of Vermont, was a 48-year-old severely disabled woman, suffering from congenital quadriplegia, patellofemoral syndrome, epilepsy, depression, and impulse control disorder. She has significant cognitive impairments, including mental retardation. She has paralysis on her right side, and has cerebral palsy on her left side causing her left leg and hand to be weak. She

requires the use of either a wheelchair or walker and needs the assistance of one and sometimes two people to go out.

53. As a result of KR's substantial physical and mental limitations, Kenneth Roberts was duly appointed as her co-guardian by the Bennington [Vermont] District Probate Court in 1998. He has full authority to act on KR's behalf, including proceeding in this action as her representative.

54. During the months at issue, from September 26, 2008, to December 18, 2008, her outings outside her home were for her medical appointments, when she was accompanied by her caregiver. At other times her caregiver has taken KR grocery shopping once a week when she was not ill.

55. Her physician ordered skilled physical therapy for her starting on September 26, 2008. Physical therapy was ordered to evaluate her functional ability, perform therapeutic exercise, teach transfer techniques and gait training, and develop a home exercise program.

56. Her claim for Medicare coverage for these physical therapy services from September 26, 2008 through December 18, 2008 was denied initially and at the redetermination level of review.

57. At the reconsideration level of review, the QIC affirmed the denial of coverage, noting that the contractor at the redetermination level had determined that "the services failed to meet Medicare criteria for coverage because therapy services may be covered when there is a reasonable expectation that the beneficiary will show measurable

improvement in performing normal daily activities." In agreeing with this assessment, the QIC held that the "submitted documentation did not support that the beneficiary had experienced an acute episode or exacerbation of chronic condition resulting in a complex functional deficit to warrant skilled therapy intervention."

58. A timely filed request for review by an ALJ resulted in a decision dated November 16, 2010 that she was not entitled to coverage for those services.

59. In making that decision, the ALJ relied on the Improvement Standard, like the lower level contractors before him, noting that "[t]he services must be provided with the expectation that the condition of the patient will improve materially in a reasonable and generally predictable period of time." Relying on that standard, the ALJ held that "one cannot determine whether there is a reasonable expectation of material improvement .... [T]he submitted documentation does not support that [KR] had experienced an acute episode or exacerbation of chronic condition resulting in a complex functional deficit to warrant skilled intervention."

60. On behalf of plaintiff KR, a timely appeal of the ALJ decision to the MAC was made by fax transmission on December 22, 2010.

Plaintiff Miriam Katz

61. Plaintiff Miriam Katz is the widow of David Katz, who died on December 25, 2010. Mrs. Katz is named as the executor in her deceased husband's will.

62. David Katz, who was 90 years old and a resident of Connecticut when he died on December 25, 2010, was hospitalized in November 2010 for metastatic rectal

cancer and a high grade intestinal obstruction.

63. He had been in a SNF since November 19, 2010. Medicare covered his stay there from November 19 through November 30, 2010.

64. On November 26, 2010, plaintiff Miriam Katz received a SNF Advance Beneficiary Notice and a generic notice, both dated November 22, 2010, notifying her that Mr. Katz would no longer be covered, effective after November 30, 2010. Upon her request for expedited review of that denial, she received an "Agreement Notice of Noncoverage" on December 2, 2010. Then, continuing the process of expedited review, she requested and received an independent reconsideration decision from the QIC dated December 3, 2010. That decision affirmed the denial of coverage because the "care you are currently receiving is considered custodial and could be performed by unskilled aides, who are trained in maintenance care."

65. Plaintiff Katz has until February 1, 2011 to request ALJ review of the reconsideration decision.

Plaintiff Edith Masterman

66. Plaintiff Edith Masterman is 79 years old and lives in Maine. She has been a paraplegic since a farming accident as a teenager. As a consequence she uses a wheelchair to get around, but has been able to remain at home with help from others. She also has been diagnosed with diabetes.

67. Over the last 10 years, she has developed a problem with pressure sores. As a consequence, her wound care doctor ordered home health care for wound care. She received this care, which was covered by Medicare, on a regular basis from

Androscoggin Home Care & Hospice (AHCH) until she was hospitalized in September 2009 for surgery to perform a skin graft to repair a pressure sore.

68. An infection occurred after the skin graft and she remained hospitalized until October 14, 2009. Upon her release from the hospital, she was admitted to a skilled nursing facility from October 14, 2009 to January 18, 2010. When she finally returned home in January 2010 her physician ordered home health care, but AHCH refused to accept her back as a patient on the grounds that it "cannot accept Edith because her Medicare will not pay for a chronic problem" and she needs long term care. AHCH informed Ms. Masterman that Medicare would not cover the wound care her doctor ordered because Medicare does not pay for care when a wound is chronic and never expected to heal.

69. Her doctors have been and are willing to order home health care.

70. Prior to her hospitalization, Medicare covered the services provided by an AHCH nurse who came to Ms. Masterman's home every other day. After her hospitalization and because she could not obtain Medicare coverage of her home health care, Ms. Masterman originally made weekly visits to the wound care clinic at the hospital. She now visits the wound care clinic once every four weeks.

71. She receives some home care services from Elder Independence of Maine, paid for by Medicaid, which includes home health aides three times daily for about 1-1/2 to 2 hours per visit from Home Care of Maine and a once weekly skilled nursing visit from Care and Comfort.

72. AHCH is the only Medicare certified home health agency in her area. Medicare-covered home health care from AHCH would be more frequent than the care

she now receives and would free her from the taxing effort and discomfort of having to go to the wound care clinic.

73. Ms. Masterman only leaves her home now for doctor or clinic appointments. Home health aides do her shopping. She cannot get in and out of bed by herself, but is able to move around her house once she is in her wheelchair.

74. Because AHCH refuses to accept her as a patient due to its belief that the Improvement Standard would deny her coverage, Ms. Masterman is not able to have a claim filed with Medicare or to obtain access to the administrative process.

Plaintiff Mary Patricia Boitano

75. Plaintiff Mary Patricia Boitano is 83 years old and lives in Rhode Island. She was hospitalized from October 22, 2010 through October 29, 2010 for a gastrointestinal hemorrhage, anemia, and renal failure, which required dialysis two days per week. Prior to being hospitalized, she lived at home with her husband.

76. On October 29, 2010 she was transferred to a skilled nursing facility, Roberts Health Centre. Medicare covered her stay there from October 29, 2010 to November 22, 2010.

77. On November 19, 2010, her husband, George Boitano, received a Notice of Non-Coverage from her Part C plan, United HealthCare, informing her that Medicare coverage for her stay in the SNF would end on November 22, 2010. George Boitano appealed the decision to end Medicare coverage.

78. On November 22, 2010, upon the request for fast-track appeal, the coverage denial was affirmed. The denial affirmation was based on the determination that "[t]herapy services must … be reasonable in relation to the expected improvement in

your condition."

79. On January 13, 2011, Ms. Boitano requested that the QIO reconsider its decision.

80. On or about November 22, 2010, Ms. Boitano was transferred by her family to a new SNF, West View Health Care Center. West View evaluated Ms. Boitano and determined that she required skilled nursing, physical therapy, occupational therapy and speech therapy.

81. West View requested United HealthCare to restart Medicare coverage based on Ms. Boitano's current skilled nursing and therapy needs. United HealthCare refused on the grounds that it had already determined that Ms. Boitano did not qualify for Medicare coverage.

82. At her own expense, Ms. Boitano remained at West View and received skilled nursing, physical therapy, occupational therapy and/or speech therapy on a daily basis from November 23, 2010 through January 3, 2011.

83. Ms. Boitano was readmitted to the hospital on January 3, 2011 with another gastrointestinal bleed.

Plaintiff National Committee to Preserve Social Security and Medicare

84. Plaintiff National Committee to Preserve Social Security and Medicare ("NCPSSM" or "the National Committee") is a nonpartisan, nonprofit nationwide membership organization representing millions of members and supporters nationwide.

85. The mission of the NCPSSM is to protect, preserve, promote, and ensure the financial security, health, and well-being of current and future generations of Americans. A central focus of that mission is the protection of Social Security and

Medicare. Eliminating the Improvement Standard is an important aspect of that overall goal.

86. The NCPSSM works through advocacy, education, services, grassroots efforts, and the leadership of the Board of Directors, its President and Chief Executive Officer (presently, former Congresswoman Barbara B. Kennelly), and the organization's professional staff.

87. NCPSSM's work is supported through annual membership dues and contributions, and through petitions and letters signed by his members and supporters. At present, it has approximately 3.2 million members and supporters throughout the country, of whom virtually all are Medicare beneficiaries. Some of the NCPSSM's members who are Medicare beneficiaries have had or are having the Improvement Standard applied to them.

88. Members of the National Committee would have standing to sue in their own right. The interests that the National Committee seeks to protect in challenging the Improvement Standard are germane to its purpose. Because this lawsuit seeks a legal ruling in the form of declaratory, injunctive and/or mandamus relief, rather than individualized relief for its members, the participation of individual members of the National Committee is not required.

89. Via certified mail on Sept. 23, 2010, counsel for plaintiff National Committee sent letters on its behalf to Defendant Sebelius and to Donald Berwick, the CMS Administrator. The identical letters informed the defendant and the Administrator that their application of the Improvement Standard was in violation of the Medicare statute and regulations, of the Administrative Procedure Act and the Freedom of

Information Act, and of the Due Process Clause of the Fifth Amendment. The letters requested that the defendant and the Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application."

90. The letters were received by Defendant Sebelius and by Administrator Berwick on October 4, 2010. Neither defendant Sebelius nor Administrator Berwick, nor anyone acting on their behalf, has responded to the letters.

Plaintiff National Multiple Sclerosis Society

91. The National Multiple Sclerosis Society (MS Society) is a nationwide organization with a 50-state network of chapters that works to eradicate multiple sclerosis by stopping disease progression and preventing the disease in future generations, while restoring function and providing and advocating for enhanced care and support for those already affected by or living with this chronic disease, including ensuring their access to quality health care, long-term care resources, and accessible, affordable insurance.

92. The MS Society accomplishes this mission by supporting comprehensive and globally collaborative research into the underlying causes, understanding, potential treatments, and ultimate prevention of multiple sclerosis, and by providing information and resources, education, and support of all kinds to people with multiple sclerosis and their families. This is accomplished in a variety of ways, including nationally-managed programs and locally-managed state programs that provide services to families: information and referrals, support groups, care consultation, research, and through educating and advocating with all appropriate agencies at the federal, state, and local levels.

93. In its effort to assist people with multiple sclerosis the MS Society works to ensure that services and benefits are available from federal programs that provide assistance to those with chronic illness and disability. As part of the MS Society's commitment to helping people affected by multiple sclerosis, the organization focuses on four key programs: Medicare, Medicare Prescription Drug Plans (Part D of Medicare), Social Security disability, and Department of Veterans Affairs benefits.

94. In its work on Medicare, the MS Society has focused in particular on the Improvement Standard as a critical factor in preventing people with multiple sclerosis from obtaining the Medicare coverage and health services that they need. Consequently, the MS Society assists people who have been denied or terminated from coverage because of application of the Improvement Standard. It also has sought to convince CMS to end Medicare's reliance on the Improvement Standard.

95. The MS Society is the functional equivalent of a membership organization, as people with multiple sclerosis and their families are represented by the MS Society and are able to express their views and to protect their collective interests through it. Its 48 chapters, which combined represent the entire United States, have members who vote, and members nationwide participate in identifying priority areas of need as part of the organizational strategic planning process.

96. Many of the individuals who act through the MS Society are Medicare beneficiaries, and a large number of them have been harmed by the Improvement Standard.

97. Individuals who act through the MS Society would have standing to sue in

their own right. The interests that the MS Society seeks to protect in challenging the Improvement Standard are germane to its purpose. Because this lawsuit seeks a legal ruling in the form of declaratory, injunctive, and/or mandamus relief, rather than individualized relief, the participation of individuals who act through the MS Society is not required.

98. Via certified mail on December 20, 2010, counsel for plaintiff MS Society sent letters on its behalf to Defendant Sebelius and to Donald Berwick, the CMS Administrator. The identical letters informed the defendant and the Administrator that their application of the Improvement Standard was in violation of the Medicare statute and regulations, of the Administrative Procedure Act and the Freedom of Information Act, and of the Due Process Clause of the Fifth Amendment. The letters requested that the defendant and the Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application."

99. The letters were received by Defendant Sebelius and by Administrator Berwick on December 28, 2010. Neither defendant Sebelius nor Administrator Berwick, nor anyone acting on their behalf, has responded to the letters.

Plaintiff Parkinson's Action Network

100. The Parkinson's Action Network (PAN) is a nationwide organization that works to eliminate Parkinson's disease and to provide better treatment for, and improve the quality of life of, people living with the disease.

101. PAN accomplishes this mission by working in partnership with other Parkinson's organizations and PAN's grassroots network of advocates in over 40 states. PAN educates the public, lawmakers, and appropriate federal agencies about the effects of Parkinson's and the need for better treatments and a cure.

102. PAN also advocates on behalf of those living with Parkinson's to ensure that benefits from federal programs, such as Social Security and Medicare, are properly made available to those who are eligible. The Improvement Standard in Medicare, which deprives Medicare beneficiaries, including those with Parkinson's, of coverage to which they are entitled, is an issue that PAN focuses on to improve the quality of life for its constituents.

103. PAN is the functional equivalent of a membership organization, as individuals with Parkinson's and their families are represented by PAN and its grassroots network, and are able to express their views and to protect their collective interests through it.

104. Many of the individuals who act through PAN are Medicare beneficiaries, and a large number of them have been harmed by the Improvement Standard.

105. Individuals who act through PAN would have standing to sue in their own right. The interests that PAN seeks to protect in challenging the Improvement Standard are germane to its purpose. Because this lawsuit seeks a legal ruling in the form of declaratory, injunctive, and/or mandamus relief, rather than individualized relief, the participation of individuals who act through PAN is not required.

106. Via first-class mail on December 10, 2010, via certified mail on December 16, 2010, and via United Parcel Service (UPS) on January 6, 2011, counsel for plaintiff PAN sent letters on its behalf to Defendant Sebelius and to Donald Berwick, the CMS Administrator. The identical letters informed the defendant and the Administrator that their application of the Improvement Standard was in violation of the Medicare statute and regulations, of the Administrative Procedure Act and the Freedom of Information Act, and of the Due Process Clause of the Fifth Amendment. The letters requested that the defendant and the Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application."

107. The United States Post Office has no record of the letters sent by certified mail on December 16, 2010 being received. The letters sent by UPS on January 6, 2011 were received by Defendant Sebelius and by Administrator Berwick on January 7, 2011. Neither defendant Sebelius nor Administrator Berwick, nor anyone acting on their behalf, has responded to the letters.

Plaintiff Paralyzed Veterans of America

108. Plaintiff Paralyzed Veterans of America (PVA) is a nationwide, congressionally chartered veterans service organization that has as its mission to use its expertise, developed since its founding in 1946, on behalf of armed forces veterans who have experienced spinal cord injury or dysfunction.

109. This expertise is employed to advocate for quality health care for its

members, for research and education addressing spinal cord injury and dysfunction, for benefits based on its members' military service, and for civil rights, accessibility, and opportunities that maximize its members' independence.

110. PVA has almost 20,000 members, of whom over 6,200 are age 65 or over. About half of the PVA membership has identified Social Security benefits, either for old-age or disability, as their main source of income. About 10,500 members have non-service-connected chronic conditions, which allow them to enroll in the Department of Veterans Affairs (VA) health care program only as low priority patients, forcing a majority of these to elect Medicare coverage, either in addition to in or instead of VA health care.

111. Furthermore, PVA members who are service-connected and enrolled in the VA health care program are free to enroll in Medicare as well and seek non-VA health care providers who accept Medicare assignment.

112. Although the exact number of PVA members who are eligible for and receiving Medicare coverage is not known, the information in the preceding paragraph indicates that thousands of PVA members are eligible for and receiving Medicare. Since virtually all PVA members have chronic conditions, some, probably thousands, of those PVA members who are Medicare beneficiaries have had or are having the Improvement Standard applied to them.

113. Members of PVA would have standing to sue in their own right. The interests that PVA seeks to protect in challenging the Improvement Standard are germane

to its purpose. Because this lawsuit seeks a legal ruling in the form of declaratory, injunctive and/or mandamus relief, rather than individualized relief for its members, the participation of individual members of PVA is not required.

114. Via certified mail on December 20, 2010, counsel for plaintiff PVA sent letters on its behalf to Defendant Sebelius and to Donald Berwick, the CMS Administrator. The identical letters informed the defendant and the Administrator that their application of the Improvement Standard was in violation of the Medicare statute and regulations, of the Administrative Procedure Act and the Freedom of Information Act, and of the Due Process Clause of the Fifth Amendment. The letters requested that the defendant and the Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application."

115. The letters were received by Defendant Sebelius and by Administrator Berwick on December 28, 2010. Neither defendant Sebelius nor Administrator Berwick, nor anyone acting on their behalf, has responded to the letters.

American Academy of Physical Medicine and Rehabilitation

116. Plaintiff American Academy of Physical Medicine and Rehabilitation (AAPM&R) is the premier medical society for the specialty of physical medicine and rehabilitation. It has more than 7,500 members and represents greater than 75% of Board certified physiatrists in the United States.

117. AAPM&R's core purpose is to advance its members' ability to serve

patients. It seeks to advance the education, knowledge, skills, and research of its members in order to provide quality care and to represent the best interests of their patients who have or are at risk of having temporary or permanent disabilities.

118. AAPM&R carries out its vision by promoting excellence in physiatric practice and advocating on public policy issues related to persons with disabling conditions and pain.

119. Among the policy issues on which it advocates is the Improvement Standard. It is the position of the AAPM&R that the Medicare statute and regulations require that Medicare provide coverage to its enrollees for the skilled medical services necessary for their care and that the need for these services may exist independent of medical improvement.

120. Members of AAPM&R would have standing to sue in their own right. The interests that AAPM&R seeks to protect in challenging the Improvement Standard are germane to its purpose. Because this lawsuit seeks a legal ruling in the form of declaratory, injunctive and/or mandamus relief, rather than individualized relief for its members, the participation of individual members of AAPM&R is not required.

121. Via first-class mail on December 14, 2010, via certified mail on December 16, 2010, and via UPS on January 6, 2011, counsel for plaintiff AAPM&R sent letters on its behalf to Defendant Sebelius and to Donald Berwick, the CMS Administrator. The identical letters informed the defendant and the Administrator that their application of the Improvement Standard was in violation of the Medicare statute and regulations, of the

Administrative Procedure Act and the Freedom of Information Act, and of the Due Process Clause of the Fifth Amendment. The letters requested that the defendant and the Administrator "direct that the Improvement Standard no longer be employed to make coverage decisions and that appropriate steps be taken to correct its present and past application."

122. The United States Post Office has no record of the letters sent by certified mail on December 16, 2010 being received. The letters sent by UPS on January 6, 2011 were received by Defendant Sebelius and by Administrator Berwick on January 7, 2011. Neither defendant Sebelius nor Administrator Berwick, nor anyone acting on their behalf, has responded to the letters.

VII. INADEQUACY OF REMEDY AT LAW AND PROPRIETY OF ISSUANCE OF A WRIT OF MANDAMUS

123. Plaintiffs suffer irreparable injury by reason of defendants' actions complained of herein. Not only are they deprived of Medicare coverage that is crucial to their health and well-being, but they also effectively lose the right to challenge that denial of coverage.

124. Plaintiffs have no adequate remedy at law. Only the declaratory, injunctive, and mandamus relief that this Court can provide will fully redress the wrongs done to plaintiffs.

125. Plaintiffs have a clear right to the relief sought. There is no other adequate remedy available to correct an otherwise unreviewable defect not related to a claim for benefits. The defendant has a plainly defined and nondiscretionary duty to provide the

relief that plaintiffs seek.

VIII. FIRST CAUSE OF ACTION: VIOLATION OF THE MEDICARE STATUTE AND REGULATIONS

126. Application of the Improvement Standard to deny coverage violates the Medicare statute, and in particular its medical necessity requirement, 42 U.S.C. § 1395y(a)(1)(A), its implementing regulations, 42 C.F.R. §§ 409.32(c), 409.44(b)(1), 409.44(a), 409.44(b)(3)(iii), and 409.44(c)(2)(iii), and the Medicare Benefit Policy Manual.

IX. SECOND CAUSE OF ACTION: VIOLATION OF THE PROCEDURAL REQUIREMENTS OF THE MEDICARE STATUTE

127. The Medicare statute prohibits the promulgation of a rule that "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals … to … receive services or benefits under this subchapter … unless it is promulgated by the Secretary" through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2). As a rule applied to Medicare beneficiaries to deny them coverage, the Improvement Standard violates this notice-and-comment requirement of the Medicare statute, which renders the rule void and of no force and effect.

X. THIRD CAUSE OF ACTION: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

128. The Administrative Procedure Act prohibits rulemaking without first publishing the rule in proposed form and allowing members of the public an opportunity to comment on the proposed rule. 5 U.S.C. § 553. As a rule applied to Medicare beneficiaries to deny them coverage, the Improvement Standard violates those notice-and-comment requirements of the Administrative Procedure Act, which renders the rule

void and of no force and effect.

XI. FOURTH CAUSE OF ACTION: VIOLATION OF THE FREEDOM OF INFORMATION ACT

129. The Freedom of Information Act requires publication in the Federal Register "of substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D). The Improvement Standard meets this criterion, but it has not been published in the Federal Register. Accordingly, it cannot be applied, and the rule is void and of no force and effect.

XII. FIFTH CAUSE OF ACTION: VIOLATION OF THE DUE PROCESS CLAUSE

130. The application of an improper standard to deny coverage contrary to the Medicare Act and controlling regulations violates the Due Process Clause of the Fifth Amendment.

XIII. SIXTH CAUSE OF ACTION: VIOLATION OF THE DUE PROCESS CLAUSE

131. The application of the Improvement Standard primarily at levels of review below the ALJ level and with the pretense that it is a proper condition of coverage has the effect of discouraging or preventing beneficiaries from seeking review at which the correct standard would more likely be applied. It therefore acts to deprive beneficiaries of their right to review in violation of the Due Process Clause of the Fifth Amendment.

XIV. PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully pray that this Court:

1. Assume jurisdiction over this action.

2. Certify at an appropriate time that this suit is properly maintainable as a

class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure.

3. Declare that defendant's application of the Improvement Standard in Medicare coverage decisions violates the Medicare statute and regulations, the notice-and-comment requirements of the Medicare statute and the Administrative Procedure Act, the publication requirement of the Freedom of Information Act, and the Due Process Clause of the Fifth Amendment.

4. Grant a permanent injunction and/or an order of mandamus

a. prohibiting defendant, her successors in office, her agents, employees, and all persons acting in concert with her from applying the Improvement Standard to make Medicare coverage decisions;

b. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to review all adverse coverage decisions for the named plaintiffs and class members that rely on the Improvement Standard and to reissue those decisions without application of the Improvement Standard;

c. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to revise any rules, provisions, guidelines, directives, or other written material under her control that supports and/or applies the Improvement Standard;

d. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to direct all entities that render Medicare coverage decisions at any level (i) to correct any internal guidelines, directives, or other written material for employees that support and apply the Improvement Standard and (ii) to educate employees as to the correct approach to coverage decisions, without

regard to an Improvement Standard, as indicated by the Medicare Act and controlling regulations; and

e. ordering defendant, her successors in office, her agents, employees, and all persons acting in concert with her to monitor all entities that render Medicare coverage decisions as to their progress in eliminating the Improvement Standard as a basis for coverage decisions.

Plaintiffs pray in addition:

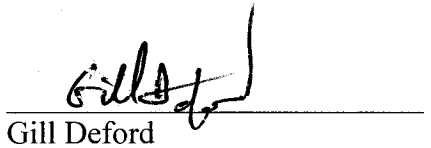
5. For costs of the suit herein.

6. For reasonable attorneys' fees and expenses pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412.

7. For such other and further relief as the Court deems just and proper.

DATED: January 13, 2011

Respectfully submitted,



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